TCT-408

De Novo Small Vessel Coronary Disease: To Stent Or Not To Stent? Can Drug Coated Balloon Be A Safe And Effective Alternative To Modern Drug Eluting Stent?

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BACKGROUND Percutaneous coronary intervention (PCI) with drug eluting stent (DES) in small vessel coronary disease (diameter <2.8 mm) has been proved superior to plain balloon angioplasty or bare metal stent with lower target lesion revascularization (TLR) rate. Drug coated balloon (DCB) has been used to treat de-novo small vessel coronary disease (SVD) with promising result and shorter dual antiplatelet therapy (DAPT) duration. The purpose of the study is to compare the safety and effectiveness of DCB in de novo SVD compared to second generation DES at 1 year.

METHODS We reviewed 3613 angioplasty cases retrospectively from 2011 to 2013 and identified 335 patients with SVD treated with device diameter $\leq$ 2.5 mm. 172 were treated with DCB only (paclitaxel-paccocath) and 163 patients treated with second generation DES (everolimus 33.7%, zotarolimus 33.7% and biolimus 32.5%) with clinical follow up at 12 months.

RESULTS There was no difference in gender (male 76.7% vs 71.8%, p = 0.32), age (mean 61.0 vs 61.2, p = 0.35), incidence of diabetes (51.2% vs 49.1%, p = 0.74), hypertension (72.7% vs 69.3%, p = 0.55), hyperlipidemia (69.8% vs 72.4, p = 0.63), and smoker (45.4% vs 46.6%, p = 0.83). DCB patients had smaller reference vessel diameter (2.22 ± 0.29 vs 2.43 ± 0.19 mm, p < 0.001), and received smaller devices (diameter 2.28 ± 0.21 vs 2.38 ± 0.12 mm, p < 0.001; length 20.2 ± 6.0 vs 22.2 ± 7.2 mm, p < 0.005) compared to the DES group. There was no significant difference on number of devices used (1.37 ± 0.6 vs 1.39 ± 0.7, p = 0.25) or the distribution of type C lesion (42.44% vs 37.79%, p = 0.66) between the DCB and DES arms. There was a trend towards larger acute lumen gain in the DES treated vessels (1.70 ± 0.48 mm) compared to DCB (1.00 ± 0.53, p = 0.09). There were more patients presenting with acute coronary syndrome (ACS) in the DCB group (77.9% vs 62.2%, p < 0.005). Despite that, patients treated with DCB received shorter duration of dual antiplatelet therapy (DAPT; 7.4 ± 4.7 months vs 11.8 ± 1.4 months, p < 0.001). Cumulative one-year events showed no difference in composite major adverse cardiac events (MACE) (11.6% vs 11.7%), p = 1.00), death (1.7% vs 3.7%, p = 0.33), myocardial infarction (5.8% vs 8.6%, p = 0.40), target lesion revascularization (5.2% vs 3.68%, p = 0.60) and stroke events (1.16% vs 0.61%, p = 1.00) between the DCB and DES arms respectively. Univariate, followed by multivariate cox-regression analysis to all risk factors and lesion characteristics revealed type C lesion as the only independent predictor of 1-year composite MACE (RR 2.52, p value < 0.05).

CONCLUSIONS In this high risk cohort of patients (>50% diabetics, 78% ACS) DCB only angioplasty delivered good clinical outcome at 1 year. The result was comparable to those treated with modern DES but has the added benefit of a shorter DAPT regime.

CATEGORIES CORONARY: Drug-Eluting Balloons and Local Drug Delivery

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Effect of drug-coated balloons in native coronary artery disease left with a dissection

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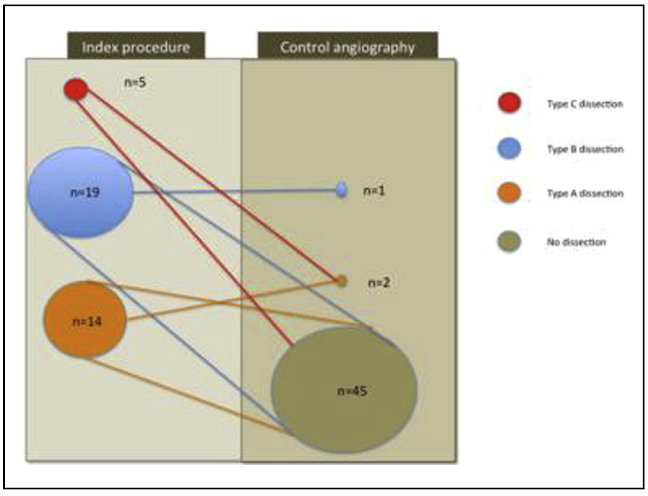
BACKGROUND Second-generation drug-coated balloons (DCB) may be an alternative to stents in selected populations for the treatment of native coronary lesions. However, the use of these devices may be hampered by a certain risk of acute vessel recoil or residual coronary dissection. Moreover, stenting after DCB has limited scientific evidence. Little is known when a not flow-limiting dissection is left after DCB-angioplasty.

METHODS This was a prospective observational study whose aim was to investigate the outcome of a consecutive series of patients with native coronary artery disease treated with second-generation DCB and residual coronary dissection at two Italian centers. We evaluated patient clinical conditions at 1 and 9 months and angiographic follow up was undertaken at 6 months.

RESULTS Between July 2012 and July 2014, 156 patients were treated with DCB for native coronary artery disease. Fifty-two patients had a final dissection, 4 of which underwent prosthesis implantation and 48 were left untreated and underwent angiographic follow up after 201 days (I.Q. range: 161-250 days). The dissections were all type A-C and none determined an impaired distal flow. Complete vessel healing at angiography was observed in 45 patients (93.8%), whereas 3 patients had persistent but uncomplicated dissections, and 3 binary restenosis (6.2%). Late-lumen-loss was 0.14mm (-0.14-0.42). Major adverse cardiovascular events occurred in 11 patients of the entire cohort and in 4 of the dissection cohort (7.2% vs. 8.1%, p=0.48). We observed 8 and 3 target-lesion revascularizations respectively (5.3% vs. 6.2%, p=0.37).



CONCLUSIONS In this cohort of consecutive patients treated with new-generation DCB and left with a final dissection, this strategy of revascularization seemed associated with the sealing of most of dissections and without significant neo-intimal hyperplasia.

CATEGORIES CORONARY: Drug-Eluting Balloons and Local Drug Delivery

KEYWORDS Dissection, Drug-eluting balloon

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Results Of Percutaneous Coronary Intervention Of "De Novo" Lesions With Sequent Please® Paclitaxel Eluting Balloon Catheter At A Very Long-Term Follow-Up

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BACKGROUND Drug eluting balloons currently constitute one of the therapeutic tools used in percutaneous coronary intervention (PCI) of de novo coronary lesions, mainly in bifurcations and small vessels. Nowadays, their results at a very long-term follow up are unclear. The main objective of this study was to evaluate the efficacy and safety of second-generation Sequent Please® paclitaxel eluting balloon (PEB) in de novo coronary lesions at 6 years.

METHODS We prospectively included 87 consecutive patients (69±12 years, 66.7% male) with 87 de novo lesions treated with PEB between March 2009 and January 2014. Additional bare metal stent (BMS) or drug-eluting stent (DES) was implanted after PEB if the result was not satisfactory because of dissection, recoil or significant residual stenosis. We evaluated the presence of major cardiac events (MACE) after a prolonged clinical follow-up (median 51 months): death, nonfatal myocardial infarction, target lesion revascularization (TLR) and thrombosis.